Serial No. 10/632,054
Examiner Phyllis G. Spivack

REMARKS

Claims 1-29 are pending in the application. Restriction is required to one of the following allegedly distinct inventions:

I. Claims 1-18, drawn to an implantable or insertable medical device, class 424, subclasses 422+;

II. Claims 19-27, drawn to a method of forming the claimed implantable or insertable medical device, classified in Class 424, subclass 422+;

III. Claim 28, drawn to methods to provide an increase in the cumulative release of a therapeutic agent from a medical device, Class 427, subclass 1+;

IV. Claim 29, drawn to methods of identifying an implantable or insertable medical device for which increased release is desired, classified in Class 427, subclass 1+.

Applicants hereby elect the Group I claims, Claims 1-18, for initial prosecution on the merits.

Pursuant to 35 U.S.C. 121, election of a single disclosed species for prosecution on the merits is also required. The species listed in the Office Action are as follows:

Claim 7: a catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch and a shunt;

Claims 14-18: distinct polymeric agents.

Applicants hereby elect the following Species:

Claim 7, a stent.

Claims 14-18, polystyrene-polyisobutylene-polystyrene triblock copolymer.

Claims 1-14 and 16-18 of Group I read upon the elected species.

Applicant notes that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species provided by 37 C.F.R. 1.141.

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The election is respectfully made with traverse, because it is believed that a search and examination of the entire application can be made without serious burden.

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (703) 433-0510 in order that any outstanding issues be resolved.

The Office is authorized to charge any fees required, to deposit account number 50-1047.

Respectfully submitted,

David B. Bonham
Registration No. 34,297

Attorney for Applicant
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Certificate of Facsimile Transmission
I hereby certify that this document and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 571-273-8300 on Oct. 2, 2006.

David B. Bonham
(Printed Name of Person Mailing Correspondence)

(Signature)

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Serial No. 10/632,054
Examiner Phyllis G. Spivack

REMARKS

Pursuant to 35 U.S.C. 121, election of a single disclosed species for prosecution on the merits is required. The species listed in the Office Action are as follows:

1. A location for implantation of the stent selected from the following (claim 8):
    1. the coronary vasculature,
    2. the peripheral vascular system,
    3. esophagus
    4. trachea,
    5. colon,
    6. biliary tract,
    7. urinary tract,
    8. prostate
    9. brain

2. A therapeutic agent selected from the following (claim 9):
    1. an anti-thrombotic agent,
    2. an anti-proliferative agent,
    3. an anti-inflammatory agent,
    4. an anti-migratory agent,
    5. an agent affecting extracellular matrix production and organization,
    6. an antineoplastic agent,
    7. an anti-mitotic agent,
    8. an anesthetic agent,
    9. an anti-coagulant,
    10. a vascular cell growth promoter,
    11. a vascular cell growth inhibitor,
    12. a cholesterol-lowering agent,
    13. a vasodilating agent,
    14. an agent that interferes with endogeneous vasoactive mechanisms

3. A range for the percentage increase for the amount of therapeutic agent with a corresponding time frame (claims 10-13).

Applicants hereby elect the following Species:

1. Coronary vasculature
2. Antiproliferative agent
3. Cumulative release of therapeutic agent increased by an amount ranging from 100% to 1000% after a period of administration of 1 week.

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Claims 1-14 and 16-18 of previously elected Group I read upon the previously and currently elected species.

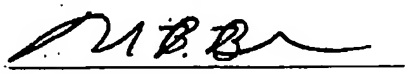
Applicant notes that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species provided by 37 C.F.R. 1.141.

The election is respectfully made with traverse, because it is believed that a search and examination of the entire application can be made without serious burden.

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (703) 433-0510 in order that any outstanding issues be resolved.

The Office is authorized to charge any fees required, to deposit account number 50-1047.

Respectfully submitted,



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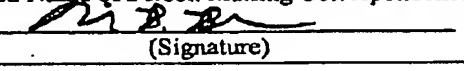

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,054	07/31/2003	Robert E. Richard	02-465	9964

27774 7590 03/05/2007

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,054	RICHARD ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The election, filed on October 2, 2006, is acknowledged. Upon reconsideration, said election supplemental by adding the following additional election requirement.

Specie Election

This application contains claims directed to the following patentably distinct species, and a choice of one from each of the following two species sets are required to be elected for examination:

1) A location for implantation of the stent selected from the following: the coronary vasculature, the peripheral vascular system, esophagus, trachea, colon, biliary tract, urinary tract, prostate or brain.

2). A therapeutic agent selected from the list in Claim 9.

3) A range for the percentage increase for the amount of therapeutic agent with a corresponding time frame, as disclosed in Claims 10 through 13.

The species are independent or distinct because, in the case of the location for implantation of the stent, a search for the placement of a stent in one system or area of the body would not necessarily yield results for another. For example, the stents utilized for coronary vasculature, which are typically metallic, would differ from the type of stent generally used in the brain, because the very narrow, fragile cranial arteries and the tight curve of the carotid siphon prevent the use of most coronary stents in the brain. In the case of the therapeutic agents, again, a search for one would not necessarily yield results for another, because the different agents may serve different functions. For example, anti-mitotic agents seek to inhibit the

development of additional cells by inhibiting cell division and replication while vascular cell growth promoters seek to increase cell populations. In the case of range for the percentage increase for the amount of therapeutic agent with a corresponding time frame, a search for one range will not necessarily yield results for another, especially given the variation of therapeutic agents disclosed.

The applicant is required under 35 U.S.C. 121 to elect a single disclosed species within each group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised to choose a range and corresponding time frame that is compatible with the therapeutic agent selected and properly disclosed in the specification, so as to avoid a rejection due to the presence of new matter. Currently, claims 1-29 are generic.

The applicant is advised that a reply to this requirement must include an identification of the species that is elected in each group consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Applicant is advised that in order for the reply to this requirement to be complete, it must include (i) an election of a species or invention to be examined even though the requirement be

traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the application. Any amendment of the inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5 March 2007
ARH

3/2/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER